

REMARKS

Claims 1-17 and 19-30 are pending. Claims 1, 7, 24 and 25 have been amended and claim 18 has been cancelled.

At the outset, Applicants wish to thank the Examiner for conducting a telephonic interview with the undersigned regarding the present application on April 10, 2006. During said interview, the various objections and rejections set forth in the Office Action were discussed along with suggested or proposed responses for advancing the prosecution of this application. With respect to the objection to the Drawings, the Examiner suggested adding more detail into the Brief Description of the Drawing section; with regard to the trademarks in the specification and claims, Applicants proposed to amend the specification and claims to be in conformance with acceptable practice; with respect to the rejection under 35 USC 102(c), Applicants proposed to amend the claims to indicate that the amine component (b) and the base component (c) are not the same compound in the composition; with respect to the rejections under 35 USC 103, the Examiner indicated that the comparative data in the specification was considered but not persuasive; as an alternative response to the 35 USC 103 rejection and obviousness double patenting rejection, Applicants proposed to amend the claims such that the claims obtain benefit back to the provisional application (Appln. No. 60/459,765, filed April 2, 2003), thus obtaining an effective filing date of April 2, 2003, and also filing a statement of common ownership under 35 USC 103(c) and a Terminal Disclaimer with respect to the primary reference of Chen et al. U.S. 6,828,301 B2. No final agreement was reached, the Examiner indicating that the amendments will be considered when presented.

The specification has been amended to update certain patent information, to appropriately identify the various trademarks used, and to make other amendments for consistency with the amended claims. The specification has also been amended to include more detail into the Brief Description of the Drawing section appearing at page 7, the inserted text being supported by the description appearing at page 40, lines 5 to 17.

Claim 1 has been amended to define both L¹ and L² as being hydrogen (as claimed in claim 18, now cancelled) and to indicate that the amine component (b) and base component (c) are

not the same compound. This latter aspect is clearly supported by the application as filed - various amines are defined at page 16, lines 6-16 and various bases are defined at page 16, line 18 to page 17, line 5, and there is no compound listed as being both the amine and the base in the composition. In addition, the specific formulation examples of the invention at page 39 have different compounds for the amine and the base (i.e., tromethamine and sodium hydroxide, respectively). Thus, it is clearly set forth in the application as filed that the amine and base components should not be the same compound in the composition.

Claim 24 has been amended to delete superfluous text relating to a trademarked material that is not necessary to define the invention as claimed, and claim 25 has been amended to replace the trademarks "Capmul MCM" and "Captex 355" with their respective, well-known generic terminology as set forth in the enclosed product data sheets from Abitec Corporation. In particular, see the "Synonyms" section of each product data sheet.

There being no issues of new matter, entry of all the foregoing amendments is respectfully requested.

I. Restriction Requirement

Applicants appreciate the Examiner's indication that the elected species has been found free of the prior art and that the search has been extended by the Examiner to embrace the generic structure of formula (I). The Examiner maintains the restriction requirement between elected Group I (claims 1-27) and Groups II to IV (claims 28-30) directed to a method of manufacturing, a method of inhibiting HCV replication and a method of treating HCV infection since claims 28-30 remain withdrawn from consideration.

Applicants appreciate the Examiner's acknowledgment (at pgs. 4-5 of the previous Office Action dated 11/1/2005) that the USPTO's Rejoinder Practice (MPEP 821.04) is applicable to the present application. In the event that the product claims of Group I are found to be allowable, Applicants request that the process (method) claims of Groups II, III and IV be rejoined in the examination under Rejoinder Practice since all these process claims depend from the product claims of Group I.

II. Objections to the Specification and Drawings

At pages 2 to 4 of the Office Action, the Examiner objects to the specification and drawings for various reasons as summarized below:

- 1) The improper use of trademarks in the specification with appropriate identification as trademarks;
- 2) The reference to Chen U.S. Appln. 10/357,919 should be updated;
- 3) The brief description of the drawings section does not adequately describe what is shown in the figures;
- 4) The drawings are objected to because of the deficiency noted in item 3) above, i.e., failure of the specification to adequately describe what is shown in the figures (the Examiner indicates that this objection may be overcome by amendment to the specification)

The specification has now been amended to address each of the above issues noted by the Examiner. Accordingly, withdrawal of these objections is respectfully requested.

III. Claim Objections

At page 4 of the Office Action, claims 1, 7 and 24 are objected to for the following reasons:

- 1) Claim 1 - for having an additional period after the structure of formula (I);
- 2) Claim 7 - for not having an “and” or “or” between the last two recited species;
- 3) Claim 24 - for having the trademark term “Cremophor EL” in parentheses.

The claims have now been amended to address each of the above issues noted by the Examiner. With respect to claim 1, Applicants’ copy of the originally filed claim did not contain an extra period, so this extra mark may have been an artifact produced during processing of the papers at the USPTO. In any event, the currently amended claim 1 does not contain an extra period. With respect to claim 24, Applicants have deleted the parenthetical term “Cremophor EL” since this term is not necessary to define the invention of this claim which is otherwise fully described. In view of the claim amendments, withdrawal of these objections is respectfully requested.

IV. Rejection Under 35 USC 112, second paragraph

Claim 25 is rejected under 35 USC 112, second paragraph, for using the trademarks Capmul[®] MCM and Captex[®] 355, since trademarks do not define static compositions. In response, this claim has been amended to replace these terms with “medium chain mono- and diglycerides” and “medium chain triglyceride”, respectively, in order to avoid any ambiguity. As previously noted, these are the respective, well-known generic terminology in the art for these products as evidenced by the enclosed product data sheets from Abitec Corporation. In particular, see the “Synonyms” section of each product data sheet. Accordingly, the amended claims are believed to be clear and withdrawal of this rejection is therefore respectfully requested.

V. Rejection Under 35 USC 102(c)

Claims 1-6, 8-22, 26 and 27 are rejected under 35 USC 102(c) as being anticipated by Chen (US 6,828,301 B2) as evidenced by Patel (US 2001/0024658 A1). The Examiner relies upon Chen as teaching a similar composition containing tromethamine, and then Patel as teaching that tromethamine is a pharmaceutically acceptable base, as well as an amine. As stated by the Examiner, this rejection is based on the interpretation that the amine and the base may be the same compound.

Claim 1 has now been amended to recite that the amine component (b) and the base component (c) are not the same compound. This is believed to obviate this anticipation rejection as Chen does not disclose any specific composition containing both an amine and a base, wherein the amine and base are not the same compound. Withdrawal of this anticipation rejection is therefore respectfully requested.

VI. Rejection Under 35 USC 103(a)

Claims 1-27 are rejected under 35 USC 103(a) as being obvious over Chen in view of Patel (as applied in the above 102 rejection) and further in view of Tsantrizos (US 6,608,027 B1).

As indicated previously, the claims have been amended to define both L¹ and L² as being hydrogen, i.e., the quinoline moiety in formula (I) is now disubstituted with R¹ and R² groups, thus incorporating the subject matter of dependent claim 18 now cancelled. By this amendment, Applicants respectfully submit that the amended claims obtain benefit back to the parent provisional application (US Appln. No. 60/459,765, filed April 2, 2003) since the presently claimed subject matter is supported therein, thus obtaining an effective filing date of April 2, 2003. As such, the primary reference Chen (US 6,828,301 B2) is only available as possible prior art under 35 USC 102(c), (f) or (g). Since the inventions of both Chen and the present application are commonly owned, Applicants have decided to take advantage of the statutory exclusion of "commonly owned" prior art found in 35 USC 103(c)(1).

STATEMENT OF COMMON OWNERSHIP:

The invention claimed in the present application and the invention disclosed and claimed in Chen, US 6,828,301 B2 were both, at the time the invention claimed in the present application was made, owned by or subject to an obligation of assignment to Boehringer Ingelheim International GmbH.

In view of the above statement, and in accordance with the procedures outlined in MPEP 706.02 I (2), Applicants respectfully submit that Chen is removed as prior art against the present application for the purposes of 35 USC 103. Accordingly, withdrawal of this rejection is respectfully requested.

VII. Nonstatutory Double Patenting Rejections

- 1) Claims 1-6, 8-22, 26 and 27 are rejected on the ground of non-statutory double patenting over claims 1-32 of Chen (US 6,828,301 B2) in view of Patel.
- 2) Claims 1-27 are rejected on the ground of non-statutory obviousness-type double patenting over claims 1-30 of Chen (US 6,828,301 B2) in view of Patel, and further in view of Tsantrizos.

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As these are non-statutory double patenting rejections, they may be overcome with a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c). Applicants herewith submit a Terminal Disclaimer with respect to the Chen patent in compliance with 37 CFR 1.321(c), thus obviating these rejections. Accordingly, withdrawal of these rejections is respectfully requested.

In view of the above amendments and remarks, Applicants respectfully submit that this application is now in condition for allowance and earnestly request such action.

If any points remain at issue which can best be resolved by way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

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